

REMARKS

I. Claim Status.

Claims 1-4 and 7-19 are currently pending and under consideration. Claims 5, 6, and 20-35 are canceled without prejudice or disclaimer. New claims 36-45 have been added. Therefore, upon entry of this Amendment, claims 1-4, 7-19, and 36-45 will be pending and under consideration.

Claims 1, 7-9, and 17 are currently amended. Claim 1 has been amended to replace "6 to 45 amino acids" with "9 to 45 amino acids" and claims 7-9 have been amended to replace "6 to about...amino acids" with "9 to about...amino acids." Support for these amendment is found within the claims as originally filed and in the specification, *e.g.*, at Example 1. Claim 17 has been amended to delete sequences 1 and 12. Claims 1 and 17 have been amended to recite that the peptide epitope sequence is substituted for the scaffold sequence. Support for this amendment is also found in the specification as filed, *e.g.*, at Example 1. Claim 1 has been amended to recite that the allergen protein is selected from the group consisting of grass pollen allergens, mite allergens, weed pollen allergens, tree pollen allergens, and insect allergens. This amendment is supported in the specification as filed, *e.g.*, at Table 8, beginning on page 100. All amendments have been made without prejudice or disclaimer or loss of Applicants' right to claim any cancelled subject matter in divisional or continuation applications.

New claims 36-45 depend from claim 1 and recite specific proteins from which the peptide epitope sequence is selected. Support for these claims is found, *e.g.*, at Table 8, beginning on page 100 of the specification as filed.

Therefore, no new matter is added by way of these amendments.

II. Claim Rejections.

(i) Rejections Under 35 U.S.C. §112, first paragraph (enablement). The Examiner has maintained the rejection of claims 1-4 and 7-19 under 35 U.S.C. § 112, first paragraph for allegedly failing to satisfy the enablement requirement. The Examiner reiterates rejections of the previous Office Action, namely that the specification as filed allegedly does not provide enablement due to inoperability of small peptide epitope sequences, especially those under 9 amino acids in length; unpredictability of maintaining structure upon inserting or substituting amino acids; and difficulty in identifying homologous sequences and unpredictability concerning reduction of IgE binding/allergenicity. Each of these rejections is addressed in turn below.

The Examiner alleges that the specification as filed does not enable peptide epitopes under 9 amino acids. In response, to advance prosecution and without conceding the validity of the rejection, Applicants have amended independent claim 1 to recite “9 to 45 amino acids” (with claims 7-9 amended, accordingly) and have amended independent claim 17 by deleting epitope sequences under 9 amino acids in length. The specification as filed shows that an epitope of 9 amino acids in length elicits a response (*see, e.g.*, Tables 4 and 5 in the Examples). Claims 2-4, 7-16, and new claims 36-45 depend from claim 1 and claim 18 and 19 depend from claim 17. Therefore, this rejection is rendered moot, and its withdrawal is respectfully requested.

The Examiner also alleges that there is no enablement for the claimed invention due to the unpredictability of maintaining structure upon inserting or substituting amino acids. In response, to advance prosecution and without conceding the validity of the rejection, Applicants have amended claims 1 and 17 to recite “wherein the peptide epitope sequence is substituted for the

scaffold sequence.” The Examples of the specification as filed provide ample enablement for one of ordinary skill in the art to make and use hybrid proteins wherein the peptide epitope sequence is substituted for the scaffold sequence, and the Examples also provide ample evidence of the efficacy of this approach in eliciting a response. Therefore, this rejection is moot, and withdrawal of this rejection is respectfully requested.

In responding to this rejection, Applicants continue to decline to characterize the peptide epitopes as linear, conformational, or some combination of these. As stated above, there is ample enablement for one of ordinary skill in the art to make and use the invention. Knowledge of the *mechanism* of the invention is not necessary to *make* and *use* the invention as claimed.

The Examiner contends that there is no enablement due to difficulty in identifying homologous sequences, which relates to unpredictability concerning reduction of IgE binding/allergenicity. In response, without conceding the validity of the rejection, Applicants have amended independent claim 1 to recite “and the allergen protein is selected from the group consisting of grass pollen allergens, mite allergens, weed pollen allergens, tree pollen allergens, and insect allergens.” Independent claim 17 specifically recites sequences for the peptide epitope. New claims 36-45 (which depend from claim 1) recite specific protein allergens.

The allergens as recited in claims 36-45 are well characterized and well known in the art. The specification at Table 8, beginning on page 100, lists several allergens. Table 8 provides journal references and/or accession numbers to public databases describing the characterization of these allergens. The numerous references and accession numbers cited in the table demonstrate that the allergen proteins are indeed well characterized. Furthermore, Table 9 in the specification, beginning on page 135, provides PDB structure files for many of the allergens, *e.g.*, Der p 2 (PDB

file: 1A9V), Der f 2 (PDB files: 1AHK and 1AHM), Bet v 1 (PDB files: *e.g.* 1B6F, 1BTv, and 1BV1), and Ves v 5 (PDB file: 1QNX). Therefore, much information on the allergens as claimed, including structural information, is readily accessible to one of ordinary skill in the art and hence, the numerous individual allergen species are enabled. The enablement of the numerous individual allergens allows Applicants to rightfully claim the genera within which the species fall: Claim 1 recites the allergen genera grass pollen allergens, mite allergens, weed pollen allergens, tree pollen allergen, and insect allergens, all of which are outlined in the specification, as above. Finally, claim 17 provides the sequences for the peptide epitope and thus also provides sufficient guidance to one of ordinary skill in the art to make and use the invention. Therefore, the claims are fully enabled by the specification as filed.

The specification fully enables one of ordinary skill in the art to make and use the invention as claimed. Therefore, the rejection under 35 U.S.C. §112, first paragraph for enablement is obviated, and its withdrawal is respectfully requested.

(ii) Rejections Under 35 U.S.C. §112, first paragraph (written description). The Examiner has rejected claims 1-4, 7-13, and 17-19 for alleged failure to satisfy the written description requirement. This rejection is traversed as below.

Claims 36-45 recite specific allergen proteins. As noted above, these allergens are listed, *e.g.*, within Table 8 of the specification which provides accession numbers and references that describe and characterize the allergen proteins. One of ordinary skill in the art would therefore recognize that Applicants had possession of the invention as claimed at the time of filing since Applicants provide ample description to produce the claimed hybrid allergen proteins based on the

allergens listed within Table 8. Furthermore, Applicants are entitled to the full embodiment of that which they have invented. Claim 1 (from which claims 2-4, 7-13, 18, and 19 depend) recites categories of allergens, as listed, *e.g.*, in Table 8, in which the specifically claimed allergens fall. Claim 17 specifically lists the sequences of the peptide epitope. Applicants thus fully describe the invention as claimed and were in possession of, and entitled to claim, the invention as recited in the present claims. Therefore, Applicants have met the requirements within the written description requirement.

The Examiner relies on *The Regents of the University of California v. Eli Lilly*, 19 F.3d 1559 to state that disclosure of a single species does not provide adequate support to claim a genus and that definition by function does not suffice in claiming a genus. However, Applicants point out that, as stated above, several species are disclosed and fully enabled within the specification. These species, specifically claimed in claims 36-45, fall within genera as claimed within claim 1. Also, since the claims recite specific genera, species, or sequences, the question of only providing a definition through function is moot. Thus, the claims meet the requirements of *Lilly* by providing non-functional characterization and having description of multiple species within the genera.

Applicants have adequately described the invention as claimed to demonstrate possession and entitlement. Therefore, withdrawal of this rejection is respectfully requested.

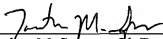
CONCLUSION

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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